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May 5, 2008

The Honorable Mary Pat Thynge United States District Court 844 King Street Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re:

Human Genome Sciences, Inc. v. Amgen, Inc. and Immunnex Corp.,

C.A. No. 07-526-SLR-MPT

Dear Judge Thynge:

Plaintiff Human Genome Sciences, Inc. ("HGS") respectfully submits this letter in response to defendants Amgen and Immunex's ("Immunex") April 21, 2008 letter (D.I. 35) seeking "clarification" of the Court's April 8 Memorandum Order (D.I. 33) ("Memorandum Order").

Although Immunex's letter is styled a "Request for Clarification," it is unclear whether Immunex is seeking reconsideration by Your Honor or review by Judge Robinson under Fed. R. Civ. P. 72(a). This ambiguity stems from Immunex's characterization of its own letter as a request for "clarification," even though Immunex also states that it intends the letter to serve as Immunex's objections under Rule 72(a). Regardless of how the Court receives the letter or what rule it is considered under, the result should be the same: Immunex's request to modify the Order should be denied, and the Memorandum Order should be affirmed.

Because there is no dispute that priority was raised during the interference which is what the Court found in its Memorandum Order—the issue of priority properly belongs in this case. The "fully developed" standard relied upon by Immunex is inapposite in this case. Moreover, Immunex incorrectly attempts to split the issue of priority in half. By definition, priority implicates analysis of two parties' invention dates, not an analysis of one party's "priority" in isolation. Therefore, in this case both parties will need to conduct discovery and present evidence at trial of each party's earliest alleged invention date.

I. Regardless of Whether Immunex Is Seeking Reconsideration or Review by the District Court Judge, Its Burden for Modifying or Reversing the Memorandum Order is High

Procedurally, it appears that Immunex's only options for obtaining review of the April 8 Order are a request for reconsideration under Delaware Local Rule 7.1.5 or a request for review by the District Court Judge under Fed. R. Civ. Proc. 72(a). Although the standards differ between the rules, the burden for changing an order under either standard is high.

The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence. Awala v. U.S. Attorney's Office Del., No. 07-110-***, 2007 U.S. Dist. LEXIS 34443, at *2 (D. Del. May 10, 2007) (citing Harsco Corp. v. Zlotnicki, 779 F.2d 906, 909 (3d Cir. 1985)). A motion for reconsideration may be granted only if the movant shows: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court issued its order; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. Id. (citing Max's Seafood Cafe v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999)). "A motion that merely raises disagreement with the Court's initial decision is not an appropriate reconsideration motion, but should be dealt with in the normal appellate process." Stepney v. Gilliard, No. 02-5259 (GEB), 2006 U.S. Dist. LEXIS 59094, at *4 (D.N.J. August 21, 2006).

Under Fed. R. Civ. P. 72(a), a district court may only reverse a Magistrate Judge's order if it finds the ruling clearly erroneous or contrary to law. Application of this standard with respect to factual issues permits reversal only if the determination "either (1) is completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bears no rational relationship to the supportive evidentiary data." Wortman v. Beglin, No. 03-495 (WHW), 2007 U.S. Dist. LEXIS 60163, at *4 (D.N.J. Aug. 16, 2007) (quoting Haines v. Liggett Group Inc., 975 F.2d 81, 92 (3d Cir. 1992)).

Although Immunex addressed its letter to Your Honor, Immunex also mentions in footnote 2 that it "intends and requests that this pleading be considered objections" under Fed. R. Civ. P. 72(a). Immunex's letter creates confusion because, whereas objections are submitted to the District Court Judge for consideration, its letter was addressed to Your Honor. Despite the ambiguity of Immunex's intentions, its criticisms of the April 8 Memorandum Order lack merit, and Immunex's request should be denied regardless of whether it is seeking reconsideration or review under Rule 72(a).

However, Immunex does not appear to have complied with Your Honor's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, which required Immunex to supply the District Judge with a courtesy copy of all filings.

This Court Articulated and Applied the Correct Legal Standard in the April II. 8 Memorandum Order

In its initial round of briefing on the scope of discovery (D.I. 22), Immunex incorrectly argued that the Court could only consider issues which were actually decided during the interference. Now, Immunex concedes that it was wrong and that issues need not be decided, but tries to restrict the issues in this § 146 action to those that were fully developed during the interference. There is no legal support for Immunex's revised legal position.

Federal Circuit precedent mandates that any issue which a party raised in the interference and insisted be resolved can be reviewed in a § 146 action. Immunex implicitly asks the Court to ignore the Federal Circuit's law and develop a new legal standard, wherein a district court can only review issues that were "fully developed" during the underlying interference. See, e.g., D.I. 35 at 3 ("The 'priority issue' before this Court ... was not fully developed and should not be considered in this 146 appeal."). This "fully developed" standard, in fact, originates from an entirely different context of interference law, and has no application here.

The "fully developed" standard only applies to the situation where the Board needs to decide whether it should terminate or continue an interference after one of the parties has already lost all of its claims. The Board's decision is meaningful because, by continuing, it subjects the initially prevailing party's patent claims to further scrutiny. For example, in Perkins v. Kwon, 886 F.2d 325 (Fed. Cir. 1989), after Perkins lost all of its claims, Kwon asked to terminate the interference. However, the Board continued and held that Kwon's claims were also invalid based on Perkin's priority of invention. Kwon appealed to the Federal Circuit and argued that the Board should have terminated the interference after Perkins lost all of its claims. The Federal Circuit held that "issues of patentability and priority that have been fully developed before the Board should be resolved by the Board." Id. at 328 (emphasis added).

The question presented in *Perkins* is when should the Board decide patentability and priority issues. The question presented to this Court in this § 146 action is when should a district court consider an interference issue for review. The correct standard for this § 146 action—which this Court previously articulated—considers whether the issue was placed before the examiner-in-chief and "one or more parties insisted that the issue be resolved." D.I. 33 at 17–18 (citing and quoting General Instrument Corp. v. Scientific-Atlanta, Inc., 995 F.2d 209, 214 (Fed. Cir. 1993) and Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994)).

Nonetheless, Immunex mistakenly applies the *Perkins* standard to the current context (see, e.g., D.I. 35 at 3), and for support, Immunex mischaracterizes the case of Rexam Indus. Corp. v. Eastman Kodak Co., 182 F.3d 1366 (Fed. Cir. 1999). The Rexam

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decision is more akin to *Perkins* than *General Instrument*. The issue in *Rexam* was not the scope of discovery in a § 146 action; the issue was whether Kodak—who lost all of its claims to Avery based on priority—could still challenge a third party's (Rexam's) claims based on priority. In permitting Kodak to challenge Rexam's patent claims, the Federal Circuit first observed that the district court properly considered the issue in the § 146 action because priority was raised during the Kodak/Rexam interference: "Issues properly raised at the Board are fair ground for litigation in the district court." Rexam Indus., 182 F.3d at 1370. The Federal Circuit then observed that not only was priority raised during the interference in that case, but it was also fully developed and decided. Thus, there was no dispute that priority was properly before the district court in the Rexam case.²

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The second case relied upon by Immunex, Goliath Hundertzente Vermoegensverwaltungsgesellschaft mbH v. Yeda Research & Development Co., No. 00-1720 (RMU), 2003 U.S. Dist. LEXIS 23349 (D.D.C. Oct. 6, 2003), is equally inapposite. There, the Board terminated an interference after invalidating the senior-party's patent claims for lack of written description. In a subsequent § 146 action filed by the seniorparty, the Court apparently limited the action to the written description issue, and decided that if the Board's dispositive decision was reversed, it would remand the case to the Board to determine 17 other motions rendered moot by its invalidity determination. Nowhere did the Court indicate that it would be improper for it to decide the 17 other issues raised below, but from a case management perspective, it simply declined to do so.

Immunex's request to restrict issues in this case to those that were "fully developed" during the interference should be denied under both the reconsideration and Rule 72(a) standards for review. Immunex does not point to an intervening change in law, new evidence, or a clear error in the April 8 Memorandum Order. Awala, 2008 U.S. Dist. LEXIS 34443 at *2. In fact, because the April 8 Order specifically anticipates Immunex's exact argument and rejects it (D.I. 33 at 21 n.85), Immunex is improperly asking the Court to simply rethink its decision: "A motion for reconsideration is not properly grounded on a request that a court rethink a decision already made." Id. (citing Glendon Energy Co. v. Borough of Glendon, 836 F.Supp. 1109, 1122 (E.D. Pa. 1993)).

Moreover, the Court always has discretion to consider the issue of priority, and Immunex has not challenged this fact. Conservolite, 21 F.3d at 1102 (stating that a district court can consider entirely new issues never raised before the Board under appropriate circumstances). For this additional reason Immunex's request should be denied.

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Indeed, if a district court could only consider "fully developed" issues, and if the Board had to decide all "fully developed" issues, then a district court could only ultimately consider decided issues—which is clearly incorrect. Conservolite, 21 F.3d at 1102; General Instruments, 995 F.2d at 214.

III. Immunex Improperly Suggests that this Court Could Split the Priority Issue into Halves

Immunex does not substantively dispute that in the underlying interference, HGS filed a priority motion, raised the issue of priority, and insisted that it be resolved—which is precisely what the Court found. D.I. 33 at 19–21.³ Instead, Immunex enigmatically attempts to carve "priority" into halves by suggesting that this "court can consider, at best, half of the priority dispute as *Immunex's priority case* was never raised or decided below." D.I. 35 at 1 (emphasis added); *Id.* at 3 ("Immunex's priority case was never raised."). There is no *half of a priority dispute*.

Although Immunex suggests that the April 8 Memorandum Order needs clarification, the Order is perfectly clear: The Court held that it "will consider the priority issue and the *parties* may conduct discovery on that issue." D.I. 33 at 21 (emphasis added). Priority, by definition, compares two parties' respective invention dates to determine who was first. Both HGS and Immunex's evidence of, *inter alia*, conception, reduction to practice, and diligence, is relevant to this case. Immunex's suggestion that the Court could even consider HGS's priority case in a vacuum (while somehow reserving Immunex's priority case for the Board) makes no sense. In this action both HGS and Immunex will attempt to establish who had the earliest date of invention, which necessarily involves Immunex's evidence of invention.

Immunex appears to be suggesting that it should be able to conduct discovery on HGS's invention date, while precluding HGS from conducting discovery on Immunex's invention date. However, without Immunex's priority evidence, this Court could not determine the ultimate issue of priority—which it has already stated it can. Not only is Immunex's suggestion inconsistent with the clear language of the Memorandum Order, but it also makes little sense from a case management perspective. Based on Immunex's proposal, this action would be remanded to the Board, only to have the Board's eventual determination subsequently reviewed under 35 U.S.C. §§ 141 or 146. The best course of action, and the one consistent with this Court's previous Order, is to allow both parties to conduct discovery and present evidence on the issue of priority in this §146 action, thereby conserving the resources of this Court, the Board, and the parties.

And finally, Immunex's implicit request to preclude HGS from taking discovery on Immunex's inventive activity should be denied under both the reconsideration and Rule 72(a) standards of review. Again, Immunex fails to point to an intervening change

HGS filed its priority brief on June 26, 2007, and thereafter, received authorization from the Board to supplement its priority brief with additional evidence, which it did on July 6, 2007. Although the Board expunged HGS's later submission of evidence, there is no dispute that HGS timely filed its priority brief.

in law, new evidence, or a clear error in the April 8 Memorandum Order. Immunex has lodged no objections to the Court's factual findings that during the interference HGS filed a priority motion, raised the issue of priority, and insisted that it be resolved. D.I. 33 at 19–21.

* * * *

The April 8 Memorandum Order needs no further clarification. To the extent Immunex's April 21 letter is treated as a request for reconsideration, HGS respectfully requests that this request be denied. And to the extent Immunex's April 21 letter is treated as objections under Rule 72(a), HGS respectfully requests that the Memorandum Order (D.I. 33) be affirmed.

Respectfully,

/s John G. Day

John G. Day

JGD/nml

cc: Richard L. DeLucia, Esquire (via electronic mail)
Melanie K. Sharp, Esquire (via electronic mail)
Michael J. Wise, Esquire (via electronic mail)